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ATYPICAL VAGINAL TEMPERATURE PATTERNS MAY IDENTIFY SUBTLE, NOT YET RECOGNISED, CAUSES OF INFERTILITY

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OBJECTIVE: To determine if averaged nocturnal vaginal temperature measurements recorded during non-menstruation by use of the OvuSense system (OS), could describe atypical patterns potentially associated with reduced fertility in volunteers with regular cycles.

DESIGN: Retrospective, longitudinal, comparative, observational study.

MATERIALS AND METHODS: 10,463 ovulatory cycles from 6,647 total users of the OvuSense (OS) device aged between 20 and 52 (where age provided), with a cycle length between 11 and 190 days (with 90% falling between 22 and 46 days). Participants used OS vaginally at night to monitor core body temperature, having voluntarily been asked to provide date of birth and identified how long they had been trying to conceive when starting use of OS. OS produces a representative overnight temperature for each night of recordings taken every 5 minutes intra-vaginally, which are then assessed with a proprietary moving averaged calculation to produce a “smooth” curve for cycle analysis. The main outcome measures were: proportions of normal and atypical OS temperature patterns as classified by observation of the smooth curve and mathematical criteria applied to the averaged readings, the frequency of their inter- and intra-participant occurrence, and associations between patterns.

RESULTS: Three novel atypical temperature patterns were identified: (a) “Crash To Baseline” - the first nightly averaged temperature falls by more than 0.2 degrees Celsius (^{0}C) to the cycle lowest temperature point (baseline) – *in 1,481 cycles (14.2%) from 1,352 OS users (20.3%)*, (b) “False Start” - a rise of more than 0.1 ^{0}C did not result in ovulation but instead a return to a baseline temperature followed by ovulation two or more days later in the cycle - *in 981 cycles (9.4%) from 939 users (14.1%)*, (c) “Crash After Ovulation” - the final temperature is more than 0.2 ^{0}C lower than the post ovulatory peak temperature - *in 1,259 cycles (12.0%) from 1,062 users (16.0%).* Additionally, Short Luteal Phase (SLP) (d) was noted with menstruation started 9 or fewer days post-ovulation - *in 871 cycles (8.3%) from 793 users (12.0%)*. SLP occurred combined with pattern (a), (b), or (c) In *237*

cycles (2.3%) from 231 users (3.5%). SLP co-existed with pattern (a) in *133 cycles from 128 users,* with pattern (b) in *155 cycles from 153 users,* and with pattern (c) in *7 cycles from 7 users.* SLP also co-existed with pattern (a) and (b) in *33 cycles from 32 users,* and as can be expected in very low frequency with patterns (a) and (c) *1 cycles from 1 user,* and (b) and (c): *2 cycles from 2 users*. Therefore 3,721 cycles exhibited one or more of the 'atypical' patterns (a), (b), or (c) = 35.6%).

CONCLUSION: It is likely that OS continuous vaginal temperature patterns closely reflect luteal progesterone changes and hence describe subtle progesterone secretion or metabolism anomalies, which have not been recognised as yet. Pattern (a) suggests a high progesterone early in the cycle, while (b) suggests an initial LH surge and accompanying small progesterone rise may not always be followed by ovulation within 48 hours. Patterns (a) and (b) would be expected to occur in women with PCOS, and further studies are planned to examine this within the OS population. Pattern (c) suggests that progesterone may fall sharply in some women before the onset of menses – and it is possible that fertility may be impaired in these cycles. The relatively strong correlation between SLP and patterns (a), (b), and/ or (c) indicates that vaginal, core-body temperature monitoring may represent a promising method of identifying previously undetectable causes of infertility in women with "normal" ovulation.

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